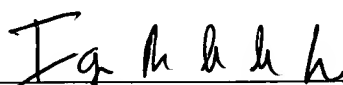
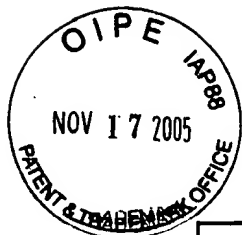




AF/1637  
JWW

TRANSMITTAL OF REPLY BRIEF			Docket No. JJJ-P02-540
In re Application of: Sampath et al.			
Application No. 09/613177	Filing Date July 10, 2000	Examiner J. N. Fredman	Group Art Unit 1637
Invention: METHODS AND COMPOSITIONS FOR IDENTIFYING MORPHOGEN ANALOGS			
<b><u>TO THE COMMISSIONER OF PATENTS:</u></b>			
Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: <u>April 19, 2005</u> .			
The fee for filing this Reply Brief is <u>\$ 500.00</u> .			
<input checked="" type="checkbox"/> Large Entity <input type="checkbox"/> Small Entity			
<input type="checkbox"/> A petition for extension of time is also enclosed.			
The fee for the extension of time is _____.			
<input type="checkbox"/> A check in the amount of _____ is enclosed.			
<input checked="" type="checkbox"/> Charge the amount of the fee to Deposit Account No. <u>18-1945</u> . This sheet is submitted in duplicate.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. <u>18-1945</u> . This sheet is submitted in duplicate.			
 _____ Ignacio Perez de la Cruz Attorney Reg. No. : 55,535 ROPES & GRAY LLP One International Place Boston, Massachusetts 02110-2624 (617) 951-7289		Dated: <u>November 15, 2005</u>	
<div style="border: 1px solid black; padding: 5px;"><p>I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.</p><p>Dated: <u>11-15-05</u>      Signature: <u>Crena Pacheco</u> (Crena Pacheco)</p></div>			



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<b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		<b>Complete if Known</b>	
		Application Number	09/613177
		Filing Date	July 10, 2000
		First Named Inventor	Kuber T. Sampath
		Examiner Name	J. N. Fredman
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Art Unit	1637
<b>TOTAL AMOUNT OF PAYMENT</b>		(\$)	500.00
		Attorney Docket No.	JJJ-P02-540

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims    Extra Claims    Fee (\$)    Fee Paid (\$)  
\_\_\_\_\_ - 20 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

Multiple Dependent Claims  
Fee (\$)    Fee Paid (\$)  
\_\_\_\_\_    \_\_\_\_\_

Indep. Claims    Extra Claims    Fee (\$)    Fee Paid (\$)  
\_\_\_\_\_ - 3 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets    Extra Sheets    Number of each additional 50 or fraction thereof    Fee (\$)    Fee Paid (\$)  
\_\_\_\_\_ - 100 = \_\_\_\_\_ / 50 \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1402 Filing a brief in support of an appeal    500.00

<b>SUBMITTED BY</b>			
Signature	<u>Ignacio Perez de la Cruz</u>	Registration No. (Attorney/Agent)	55,535
Name (Print/Type)	Ignacio Perez de la Cruz	Telephone	(617) 951-7289
		Date	November 15, 2005

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 11-15-05    Signature: Crena Pacheco (Crena Pacheco)



I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 11-15-05 Signature: Crena Pacheco  
(Susan Lanney)

Docket No.: JJJ-P02-540  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Sampath et al.

Application No.: 09/613177

Confirmation No.: 8978

Filed: July 10, 2000

Art Unit: 1637

For: METHODS AND COMPOSITIONS FOR  
IDENTIFYING MORPHOGEN ANALOGS

Examiner: J. N. Fredman

**APPELLANT'S REPLY BRIEF**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is in furtherance of the Notice of Appeal, filed April 19, 2005, and in reply to the Examiner's Answer mailed September 15, 2005.

**I. Status of Claims**

Claims 1-10, 13, 15, 30-33, 36 and 43-50 are pending in the application and are involved in this Appeal. Claims 1 and 36 are independent claims; all other pending claims depend upon one or more of these two independent claims. No claims have been allowed. Claim 48 is objected to but otherwise allowable.

**II. Argument**

The Examiner's Answer withdraws the rejection of claims 1, 13, 36, 43 and 45-50 under 35 USC § 103 over Harris in view of Smart and further in view of Ozkaynak.

The Examiner's Answer maintains the rejection of claims 1-3, 6, 9, 13, 36, 43-47, 49 and 50 under 35 U.S.C. 103(a) over Harris in view of Smart and in further view of Nadal-Ginard.

Appellants respectfully traverse this rejection, and submit that the claims are not obvious under

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35 U.S.C. 103(a) because the combined references fail to teach all the claim limitations and because no motivation exists to combine the references.

A. Failure of Examiner to Show How References Might Teach all the Claim Elements

Appellants reaffirm their position that Harris in view of Smart and in further view of Nadal-Ginard fail to teach each of the elements of claim 1. The reasons were set forth in the Appeal Brief and will not be reproduced here. Rather, Appellants will show in this section of the Reply Brief how the Examiner's Answer fails to show how the combination of the three references might to teach or suggest all the elements of claim 1.

The disputed element of claim 1 recites "a transcription activating element that is responsive to, and distinct from the gene encoding, said morphogen." The transcription activating element (TAE) then contains two sub-elements. First, the TAE must be responsive to a morphogen. And second, the TAE must be distinct from the gene encoding said morphogen. Accordingly, if the combination of the cited references does not teach a TAE having both of these sub-elements, the combination cannot render claim 1 obvious.

The Examiner's Answer correctly recites the disputed element in the bridging sentence between pages 8 and 9. It also apparently acknowledges that the element contains two sub-elements: "[t]he transcription activating element of the claim is therefore any element which is responsive to OP-1 ...so long as that element is distinct from the specific gene." (Page 9, lines 10-12). But two sentences later, it concludes, without any basis, that the disputed limitation is to be interpreted as containing only the second sub-limitation: "[t]herefore, in interpreting this claim, any transcription activating element that is not the element of a morphogen at issue will meet the limitation of the claims." (Page 9, lines 15-16).

Appellants submit that the Examiner may not arbitrarily choose which claim elements to consider and which to ignore. "Interpreting the claimed invention as a whole requires consideration of all claim limitations. Thus, proper claim construction requires treating language in a process claim which recites the making or using of a nonobvious product as a material limitation." MPEP 2116.01 (emphasis added). The appealed claims are process claims which recite the use of a nonobvious product *i.e.* the TAE. This requirement to consider all elements of the claims is equally applicable to obviousness rejections, as stated in MPEP 2143.03:

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

To provide another example, a recent CAFC case corrected a judge's interpretation which ignored a term, *i.e.*, *Callicrate v. Wadsworth*, CAFC 04-1597-98, decided 10/31/05: "To that degree, the district court's interpretation does not fully reflect the claim language. See *Playtex Prod., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 909-10 (Fed. Cir. 2005) (claim construction was flawed in part because it read "substantially flattened" as "flat," effectively ignoring the "substantially" qualifier in the claim)."

In spite of this absolute requirement, the Examiner has failed to consider all the features of the claims. The claims plainly states that the TAE must be (i) responsive to a morphogen; and (ii) distinct from the morphogen gene. Yet the Examiner has failed to consider the first of these sub-limitations in his analysis of patentability. This is further evidenced from the analysis of the bridging paragraph on page 9, lines 17-19, where the Examiner proceeds to analyze a TAE "amputated" of one of its two sub-limitations: "Harris teaches all of the elements of claim 1 except for the use of a transcription activating element that is distinct from the gene encoding the morphogen...Nadal Ginard teaches the final element, the use of a transcription activating element that is distinct from the gene encoding the morphogen" The rest of this section of the Examiner's Answer alleges that the combination of references teach the "amputated" TAE lacking one of its two sub-limitations. But even if the Examiner's Answer successfully showed how the combined references taught the first sub-limitation, which appellants do not concede, it fails show how the combination might teach or suggest the second sub-limitation.

By failing to show how the combined references might teach or suggest a TAE responsive to a morphogen, the Examiner's Answer fails to teach a sub-element of claim 1 and thus fails to teach or suggest how the references might teach all of the elements of claim 1. MPEP 706.02(j) requires, among other things, that the prior art references teach or suggest all the claim elements. By not showing how the combination of references teach or suggest all the claim elements, the Examiner has failed to meet his burden under MPEP 706.02(j).

#### B. Failure of References to Teach all the Claim Limitations

Not only has the Examiner failed to show how the references teach a transcription activating element having the two sub-elements stated above, the references simply do not teach the TAE of claim 1. The Examiner concedes on page 9, last paragraph, that Harris and Smart do not teach even the amputated TAE. The Examiner turns to Nadal-Ginard to find a teaching or suggestion of the TAE. But Nadal-Ginard fails to recite any specific morphogens, such as those in dependent claim 45. Nadal Ginard fails to teach or suggest that a TAE can be responsive to a morphogen. Nadal-Ginard fails to even recite the term “morphogen” anywhere in its text, which the Examiner concedes is true. How, then, can Nadal-Ginard teach the use of a TAE that is responsive to a morphogen? It can’t. And the Examiner has not and cannot show how it might.

Even assuming, arguendo, that Nadal-Ginard had disclosed the nucleic acid sequence of the mouse collagen gene as in the instant invention, Nadal-Ginard would not have taught that a morphogen could regulate its expression, much less teach which particular sequences from the collagen gene constitute the TAE. Nadal would not have taught one skilled in the art the TAE of claim 1.

#### C. Lack of Motivation to Combine Smart/Harris/Nadal-Ginard

Applicants maintain that no motivation existed to combine the references as previously set forth in the Appeal Brief. The Examiner’s Answer fails to show why one skilled in the art would have combined Harris and Smart. The Examiner’s Answer has not shown why one skilled in the art would have combined Harris’ screening system based on morphogen-gene promoters with Smart’s screening system based on morphogen proteins to generate screening assay which has neither morphogen promoters nor morphogen proteins.

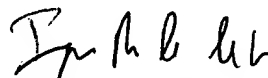
Let’s suppose for argument’s sake that a screening system lacking morphogen promoters, lacking morphogen proteins, and lacking TAE that is responsive to a morphogen could be derived by combining the teachings of Smart and Harris. Why would one turn to Nadal-Ginard for a TAE that is responsive to a morphogen, when Nadal-Ginard fails to teach such a TAE or anything related to a morphogen? As stated in the preceding sections, Nadal Ginard does not teach that a particular sequence will suffice as a TAE responsive to a morphogen, and even fails to include the term “morphogen”, or to describe any of the specific morphogens recited in the instant claims, anywhere in its specification.

**CONCLUSION**

Applicant believes no fee is due other than the \$500 fee for filing an Appeal Brief. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. JJJ-P02-540 from which the undersigned is authorized to draw.

Dated: November 15, 2005

Respectfully submitted,

By 

Ignacio Perez de la Cruz

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